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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,692	03/31/2004	John C. Stroebel	P20243.00	7240

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EXAMINER

WU, EUGENE TONG

ART UNIT PAPER NUMBER

3766

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,692

Applicant(s)

STROEBEL, JOHN C.

Examiner

Eugene T. Wu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/02/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 13-17, 19, 20, 23-25, 36-38, 49 and 51-53 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 21, 22 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-12, 27-35, 39-48, 50 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/21/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to:

11/02/2006 – Applicant response to Misc. Action
10/12/2006 – Misc. Action
09/25/2006 – Applicant response to Restriction Requirement
09/11/2006 – Restriction Requirement

Election/Restrictions

1. Applicant's election with traverse of Species III, directed to claims 1-12, 18, 21, 22, 26-35, 39-48, 50, and 54, on the reply dated 11/02/2006 is acknowledged.

2. Claims 13-17, 19, 20, 23-25, 36-38, 49, and 51-53 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/02/2006.

3. Applicant's election with traverse in the reply filed on 11/02/2006 is acknowledged. The traversal is on the ground(s) that adding different modes of operation to a base mode FIDDI does not define separate species. Applicant asserts that Species II, referred to as the "base mode" of FIDDI in the Office Action mailed on 09/11/2006, is generic to both species III and IV.

Additionally, Applicant asserts Species I is not a separate species when considered with the full application in context, and further identifies claim 20 relating to Species V. This is not found persuasive because of the following reasons:

- a. Species I (Figure 7): Claims 24 and 25 are directed to switching between an atrial based pacing mode and a dual chamber mode. The specification defines atrial based pacing in Paragraph 150. This is a separate species from FIDDI because FIDDI explicitly excludes mode-switching in its base mode (Paragraph 128). Furthermore, the specification makes a

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clear delineation between FIDDI and DDI (Paragraph 114). Lastly, the claims do not mention flagging.

b. Species II (Figures 11, 12A, 12B): The base mode of FIDDI is described in Paragraphs 114-129. As described in the specification and illustrated in the figures, the base form of FIDDI is capable of pacing the heart at a halved ventricular rate with a normal atrial rate (Paragraph 127). This has a different effect than the species described below. The Office also points out that Applicant refers to this species as "FIDDI in its base form" in Paragraph 121, and thus the Office is in no way indicating any claims to be generic when using the term "base" to describe this embodiment.

c. Species III (Figure 13): FIDDI with mode switching is described in Paragraphs 130-133. This species does not appear to be capable of pacing at a halved ventricular rate with normal atrial rate because the device mode switches to DDD and continues to deliver ventricular pacing pulses after the first instance of loss of intrinsic ventricular activity (Figure 13). Thus, this species has a different effect than FIDDI in its base form.

d. Species IV (Figure 14): FIDDI with a mode supervisor is described in Paragraphs 134-138. In particular, the mode supervisor requires circuitry capable of keeping a memory of past ventricular activity for a number of cycles, whereas FIDDI in its base form does not require this memory. Additionally, the mode supervisor allows multiple missed or skipped ventricular beats without a mode switch, whereas the mode switching species allows only one missed ventricular beat. Furthermore, Paragraph 139 mentions mode switching and a mode supervisor only in the alternative.

e. Species V: FIDDI with FAPTT is described in Paragraphs 140-142.

The requirement is still deemed proper and is therefore made FINAL.

Priority

4. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/246,816, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The prior-filed application does not show setting flags. Accordingly, claims 1-54 are not entitled to the benefit of the prior application.

Information Disclosure Statement

5. The information disclosure statement filed 03/21/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

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- a. Figure 13: T1, T2, and T3 are mentioned in Paragraph 130 but not shown in the figure.
- b. Figure 13: The top row does not show setting flags while in the DDD mode (T5, T7, and ensuing Vp), whereas the bottom row does show setting flags while in the DDD mode (Vp before T9, T9). The specification appears to support setting flags while in the DDD mode (Paragraph 132, lines 5-8). Applicant is asked to clearly indicate on the drawing(s) when and where flags are set.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities:
 - a. Paragraph 38: The "7" appearing at the end of the sentence appears to be extraneous. Appropriate correction is required.

Claim Objections

8. Claims 12, 32, 34, and 50 objected to because of the following informalities:
 - a. Claim 12, line 2: "at lease" should be "at least".
 - b. Claim 32, line 3: "initiate and VA interval" should be "initiate a VA interval".
 - c. Claim 34: "the subsequent interval" lacks antecedent basis in the claims.

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d. Claim 50: The last two lines of the claim appear to be a separate claim and should be deleted from claim 50.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-10, 27, 28, 30, 34, 39-48, 50, and 54 rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin et al. (US 5,540,725).

Regarding claim 1, Bornzin discloses the same invention substantially as claimed, including setting a flag 250 and precluding a ventricular pacing pulse 246 (Figure 14).

Regarding claims 2 and 3, Bornzin discloses the flag being valid for a cardiac cycle immediately succeeding the given cycle and the flag being valid for only one cardiac cycle subsequent to the given cycle (Figure 14).

Regarding claim 4, Bornzin discloses a P-to-P interval, which is considered equivalent to Applicant's A-A interval (Col. 11, line 44).

Regarding claim 5, Bornzin discloses setting a flag both during an AV interval 242-250 or during the VA interval 248-250, which is considered equivalent to Applicant's ventricular activity occurring at any time during the A-A interval (Figure 14).

Regarding claim 6, Bornzin discloses starting a PV/AV interval 240 and an AEI 230 (Figure 14; see also Figure 7: PVI 104 and AEI), together which are considered equivalent to Applicant's atrial escape interval.

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Regarding claim 7, Bornzin discloses delivering an atrial pacing pulse 238 (Figure 14).

Regarding claim 8, Bornzin discloses sensing a P-wave 234, which is considered equivalent to Applicant's intrinsic atrial depolarization (Figure 14).

Regarding claim 9, Bornzin discloses inhibiting a scheduled atrial pacing pulse 238 via the YES pathway of 234 (Figure 14).

Regarding claim 10, Bornzin discloses initiating an AV interval 240 while the flag is absent 224, delivering a ventricular pulse 248, setting the flag 250, and initiating PVARP/AEI timers 230 (Figure 14; see also Figure 7: 110 and AEI), which is considered equivalent to Applicant's VA interval.

Regarding claim 27, Bornzin discloses setting a flag 250, determining if the flag is present 246, starting an atrial escape interval (described above regarding claim 6), initiating an AV interval 240, delivering a pacing pulse 246, and initiating a VA interval (described above regarding claim 10) (Figure 14).

Regarding claim 28, Bornzin discloses both intrinsic 242 and paced 248 ventricular activity (Figure 14).

Regarding claim 30, Bornzin discloses no ventricular pace delivered (NO at 246) (Figure 14).

Regarding claim 34, Bornzin discloses sensing P-waves 234 and R-waves 242 which inhibit a scheduled pacing pulse 238 or 248 (Figure 14).

Regarding claim 39, Bornzin discloses setting a flag 250, determining whether the flag has been set 246, acting in a first manner (YES at 246), and acting in a second manner (NO at 246) (Figure 14).

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Regarding claims 40 and 41, Bornzin discloses storing or latching the occurrence of certain events for later referencing (Col. 12, line 37), which is considered equivalent to Applicant's placing or removing information in a memory.

Regarding claim 42, Bornzin discloses the flag being valid for only the second cardiac cycle (Figure 14).

Regarding claims 43 and 44, Bornzin discloses presence of ventricular activity 242 or 248 (Figure 14).

Regarding claim 45, Bornzin discloses starting a PV/AV interval 240 and an AEI 230 (Figure 14), also shown as PVI 104 and AEI (Figure 7), together which are considered equivalent to Applicant's atrial escape interval.

Regarding claim 46, Bornzin discloses inhibiting ventricular pacing 246 (Figure 14).

Regarding claim 47, Bornzin discloses initiating an AV interval 240, delivering a pacing pulse 248, and initiating PVARP/AEI timers 230 (see also Figure 7: 110 and AEI), which is considered equivalent to Applicant's VA interval.

Regarding claim 48, Bornzin discloses the process repeating, thereby setting a second flag valid for a third cycle (Figure 14).

Regarding claim 50, Bornzin discloses an atrial lead 15, a ventricular lead 17, a memory 40, a processing module 26, and a controller 26 (Figure 1), capable of setting flags in a first cardiac cycle, determining whether the flag has been set in a second cardiac cycle, initiating an atrial escape interval, precluding ventricular pacing, initiating an AV interval and ventricular pulse as previously described above and shown in Figure 14.

Regarding claim 54, Bornzin discloses setting a flag 250 and delivering a pulse only if the flag is absent (NO at 246) (Figure 14).

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Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 11 and 31-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin (US 5,540,725) as applied to claims 10 and 27 above, in view of Baker et al. (US 2002/0128687).

Bornzin discloses the same invention, as described above. Bornzin does not disclose restarting the VA interval. However, Baker teaches both stopping and resetting the VA timer upon a ventricular sense in order to ensure proper pacing of the heart (Paragraph 19). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the resetting of the VA interval of Baker with the method of Bornzin for the purpose of ensuring proper pacing of the heart.

13. Claims 12 and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin (US 5,540,725) as applied to claims 10 and 27 above, in view of Amblard et al. (2004/0010292).

Bornzin discloses the same invention, as described above. Bornzin does not disclose switching to a dual chamber mode. However, Amblard teaches switching to a DDD mode in order to respond to atrio-ventricular block (Paragraph 3). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the mode switching to a DDD mode of Amblard with the method of Bornzin for the purpose of responding to atrio-ventricular block.

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14. Claim 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin (US 5,540,725) as applied to claim 27 above.

Bornzin discloses the same invention, as described above. Bornzin does not disclose expressly an AV interval of 80 ms. Instead, Bornzin discloses a PV interval of 150 ms (Figure 17, see top legend). The Examiner takes Official Notice that it is well-known in the art to shorten the AV delay in order to deliver a support pulse when necessary, for example, after a skipped or missed ventricular beat. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to shorten the AV interval of Bornzin in order to deliver a support pulse when necessary.

Allowable Subject Matter

15. Claims 18, 21, 22, and 26 allowed.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

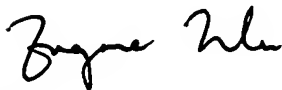
- a. Amblard (US 2004/0010292) shows a DDD/AAI operating mode that allows missed ventricular beats.
- b. Sholder (US 5,334,220) shows setting flags to inhibit v-pace.
- c. Reuter (US 4,523,593) shows settings flags to inhibit v-pace.
- d. Casavant (US 5,954,755) shows an ADI-DDI mode switching to enable 2:1 pacing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eugene T. Wu whose telephone number is (571) 272-3109. The examiner can normally be reached on M-F: 9 AM - 5 PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ETW

11/28/2006



Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766